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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,054	05/31/2001	Gunther Berndt	49589	7665

26474 7590 09/05/2003

KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

EASHOO, MARK

ART UNIT	PAPER NUMBER
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1732

DATE MAILED: 09/05/2003

Handwritten signature

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,054

Applicant(s)

BERNDL ET AL.

Examiner

Mark Eashoo, Ph.D.

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1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b).
An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Newton (US Pat. 5,683,719).

Newton teaches extruding a pharmaceutical mixture using a planetary roller extruder (4:3-14 and 1:34-40). It is inherent that all polymeric materials are to some degree heat and/or shear sensitive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

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to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breitenbach et al. (US Pat. 6,221,368) in view of Newton (US Pat. 5,683,719) and Muller (US Pat. 4,268,176).

Regarding claim 1: Breitenbach et al. teaches the basic claimed process for producing solid forms, comprising: melt extruding (9:15-23); at least one active pharmaceutical agent (1:64-2:2 and 6:59-7:63); and forming a string (9:56-66). It is noted that hot-cut pelletization extrudes multiple strings from a die wherein the string are cut at the die face.

Breitenbach et al. further teaches using various extruders, including multi-screw extruders (8:64-9:5). Although Breitenbach et al. does not distinctly teach a planetary roller extruder, Newton teaches using a planetary roller extruder (ie. rotary cylinder extruder) for processing pharmaceutically active materials. At the time of invention a person having ordinary skill in the art would have found it obvious to have used a planetary roller extruder, as taught by Newton, in the process of Breitenbach et al., and would have been motivated to do so as an equivalent alternative to form the pharmaceutical mixture. Muller is cited as evidence that planetary roller extruder is a type of multi-screw extruder (see Figs.).

Regarding claims 2-3: Muller teaches a planetary extruder with eight spindles (2:31-33). The motivation to use sure extruder is for the same reason as set forth above.

Regarding claim 4: Breitenbach et al. further teaches extruding without kneading disks (8:64-9:5).

Regarding claim 5: Breitenbach et al. does not teach a specific dwell time for the extrusion process. Nonetheless, Newton teaches that such process parameter are known to be optimized (4:2-21). At the time of invention a person having ordinary skill in the art would have found it obvious to have optimized the process parameter (inclusive of dwell time), as taught by Newton, in the process of Breitenbach et al., and would have been motivated to do so in order to optimize energy cost and avoid damaging the active material by over processing.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Krull et al., MacFarlane et al. '556 and '933, Kolossow, Brand, DE 198 31 703, and DE 196 37 479 all teach the basic state of the art.

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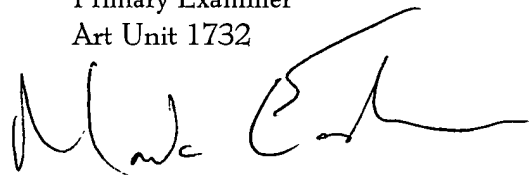
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Eashoo, Ph.D. whose telephone number is (703) 308-3606. The examiner can normally be reached on 7am-3pm EST, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on (703) 305-5493. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Mark Eashoo, Ph.D.
Primary Examiner
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A handwritten signature in dark ink, appearing to read 'Mark Eashoo', with a long horizontal flourish extending to the right.

me
2-Sep-03